IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

CEPHALON, INC. and CEPHALON FRANCE,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 1:10-cv-22997-UU
APOTEX CORP. and APOTEX INC.,	)	JURY TRIAL DEMANDED
Defendants.	)	

ANSWER, DEFENSES AND COUNTERCLAIMS OF DEFENDANTS APOTEX INC. AND APOTEX CORP.

Defendants Apotex Inc. and Apotex Corp. hereby answer the Complaint of Plaintiffs Cephalon, Inc. and Cephalon France (collectively, "Cephalon") as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 20-1514 submitted by Apotex to the United States Food and Drug Administration ("FDA") for approval to market generic copies of Cephalon's successful Nuvigil® pharmaceutical products that are sold in the United States. Nuvigil® (armodafinil) is a prescription drug widely used to improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, and shift work sleep disorder.

ANSWER: This Paragraph contains Plaintiffs' characterization of their action to which no answer is required. Insofar as an answer is required, Apotex Inc. and Apotex Corp. deny all allegations of this Paragraph, except to admit that Apotex Inc. submitted an ANDA No. 20-1514 to the FDA seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Apotex Inc.'s proposed product, Armodafinil 50 mg, 150 mg, and 250 mg tablets ("Apotex's Proposed Product") prior to expiration of U.S. Reissue Patent No. RE 37,516 (the "'516 Patent"), U.S. Patent No. 7,132,570 (the "'570 Patent") and U.S. Patent No. 7,297,346 (the

"'346 Patent"). Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

2. Cephalon, Inc. is a Delaware corporation having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon, Inc. is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

ANSWER: Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

3. Cephalon France is a société par actions simplifiée ("SAS") under the laws of France, a wholly-owned subsidiary of Cephalon, Inc., and located at 20 Rue Charles Martigny, 94701 Maisons-Alfort Cedex, France.

ANSWER: Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

4. Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

ANSWER: Admitted.

5. Apotex Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Admitted.

6. On information and belief, the acts of Apotex Corp. complained of herein were done at the direction of, with the authorization of, and/or the cooperation, participation, and assistance of, and at least in part for the benefit of, Apotex Inc.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. served as the authorized U.S. agent for ANDA No. 20-1514 pursuant to 21 C.F.R § 314.50(a)(5). Except as

specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this paragraph.

JURISDICTION AND VENUE

7. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue in this Court is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Apotex Inc. and Apotex Corp. consent to subject matter jurisdiction and venue in the United States District Court for the Southern District of Florida for the limited purposes of this action.

8. On information and belief, this Court has personal jurisdiction over Apotex Corp. and Apotex Inc. by virtue of their consent and/or contacts with this forum, including, *inter alia*, marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

ANSWER: Paragraph 8 states legal conclusions to which no answer is required. To the extent an answer is deemed required, Apotex Inc. and Apotex Corp. do not contest personal jurisdiction in the United States District Court for the Southern District of Florida for the limited purposes of this action.

9. In a prior, unrelated litigation, Apotex admitted that this District has personal jurisdiction over both Apotex Corp. and Apotex Inc. *Alcon v. Apotex Inc. & Apotex Corp.*, C.A. No. 1:06-cv-01642-RLY-TAB, D.I. 23 at 7 (S.D. Ind. Dec. 13, 2006).

ANSWER: Admit that D.I. 23 in C.A. No. 1:06-cv-01642-RLY-TAB contains the statement that S.D. Fla. has personal jurisdiction over Apotex Inc. and Apotex Corp.

10. On information and belief, Apotex Corp. has its principal place of business in this District and has designated the Corporation Service Company, 1201 Hays Street, Tallahassee, Florida 32301, as its registered agent in Florida for service of process.

ANSWER: Apotex Corp. admits that it has a principal place of business in this district. Apotex Corp. further admits that the website of the Florida Department of State Division of Corporations currently lists Corporation Service Company, 1201 Hays Street,

Tallahassee, Florida 32301 as Apotex Corp.'s registered agent. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

11. On information and belief, Apotex Corp. and Apotex Inc. both regularly conduct business in this judicial district.

ANSWER: Apotex Inc. and Apotex Corp. do not contest personal jurisdiction in the United States District Court for the Southern District of Florida for the limited purposes of this action and therefore no further answer is required. To the extent a further answer is required, Apotex Inc. and Apotex Corp. admit that Apotex Inc. manufactures numerous quality generic drugs for sale and use throughout the United States and that Apotex Corp. sells generic drug products manufactured by Apotex Inc. and other drug manufacturers throughout the United States, including in this judicial district. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

12. On information and belief, Apotex Corp. and Apotex Inc. each have continuous and systematic general business contacts with this judicial district.

ANSWER: Apotex Inc. and Apotex Corp. do not contest personal jurisdiction in the United States District Court for the Southern District of Florida for the limited purposes of this action and therefore no further answer is required. To the extent a further answer is required, Apotex Inc. and Apotex Corp. admit that Apotex Inc. manufactures numerous quality generic drugs for sale and use throughout the United States and that Apotex Corp. sells drug products manufactured by Apotex Inc. and other drug manufacturers throughout the United States, including in this judicial district. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

13. On information and belief, Apotex Inc. is in the business of formulating, manufacturing, and commercializing generic pharmaceutical products, which it distributes, markets, and/or sells in this judicial district and throughout the United States.

ANSWER: Apotex Inc. and Apotex Corp. do not contest personal jurisdiction in the United States District Court for the Southern District of Florida for the limited purposes of this action and therefore no further answer is required. To the extent a further answer is required, Apotex Inc. admits that it manufactures numerous quality generic drugs for sale and use throughout the United States, including in this judicial district. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

14. On information and belief, Apotex Corp. is the marketing and sales agent for Apotex Inc. in the United States.

ANSWER: Apotex Inc. and Apotex Corp. do not contest personal jurisdiction in the United States District Court for the Southern District of Florida for the limited purposes of this action and therefore no further answer is required. To the extent a further answer is deemed required, Apotex Inc. and Apotex Corp. admit that Apotex Corp. sells drug products manufactured by Apotex Inc. and other drug manufacturers throughout the United States, including in this judicial district. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

15. On information and belief, Apotex Inc., itself and through its agent, Apotex Corp., distributes, markets, and/or sells generic drugs in this judicial district and throughout the United States.

ANSWER: Apotex Inc. and Apotex Corp. do not contest personal jurisdiction in the United States District Court for the Southern District of Florida for the limited purposes of this action and therefore no further answer is required. To the extent a further answer is required, Apotex Inc. and Apotex Corp. admit that Apotex Inc. manufactures numerous quality generic drugs for sale and use throughout the United States and that Apotex Corp. sells drug products manufactured by Apotex Inc. and other drug manufacturers throughout the United States,

including in this judicial district. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

16. On information and belief, Apotex Inc., itself and through its agent, Apotex Corp., derives substantial revenue from the sale of Apotex Inc. products, including from sales of Apotex Inc. products in this judicial district and throughout the United States.

ANSWER: Apotex Inc. and Apotex Corp. do not contest personal jurisdiction in the United States District Court for the Southern District of Florida for the limited purposes of this action and therefore no further answer is required. To the extent a further answer is deemed required, Apotex Inc. and Apotex Corp. admit that Apotex Inc. manufactures numerous quality generic drugs for sale and use throughout the United States and that Apotex Corp. sells drug products manufactured by Apotex Inc. and other drug manufacturers throughout the United States, including in this judicial district. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

17. Apotex Inc.'s U.S. website states that Apotex Corp. is a wholly owned affiliate of Apotex Inc.

ANSWER: Apotex Inc. and Apotex Corp. admit that as accessed on September 8, 2010, the statement "Apotex Corp. is a wholly owned affiliate of Apotex Inc." is found on the website www.apotex.com, and the Court is referred to that website for a full and complete statement of its contents. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

18. On information and belief, Apotex Corp. and Apotex Inc. are two arms of the same business group, operate in concert with each other, and enter into agreements with each other that are nearer than arms length.

ANSWER: Denied.

19. On information and belief, Apotex Corp. and Apotex Inc. are jointly controlled by Dr. Bernard C. Sherman through a series of shell corporations: Apotex Corp. is a wholly-owned subsidiary of Aposherm Inc., which is a wholly-owned subsidiary of Apotex Holdings; Apotex

Holdings owns all of the outstanding capital stock of Apotex Inc. such that Apotex Corp. and Apotex Inc. are sister corporations owned by Apotex Holdings, which is controlled by Dr. Bernard C. Sherman through The Bernard Sherman 2000 Trust.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. is a Delaware corporation that is a wholly owned subsidiary of Aposherm, Inc.; Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holding Inc.; Apotex Holding Inc. owns a majority of the interest in Apotex Pharmaceutical Holding Inc. and 100% of Aposherm Inc. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

20. On information and belief, the web site of Apotex Corp., *www.apotexcorp.com*, is registered to "Apotex, 150 Signet Drive, Weston, ON M9L 1T9, CA", and the administrative and technical contact listed by the internet registrar for apotexcorp.com is an employee of Apotex Inc. The website *www.apotexcorp.com* automatically directs users to *www.apotex.com/us/en.* On further information and belief, Apotex Inc.'s website directs U.S. customers to the same web address, *www.apotex.com/us/en.*

ANSWER: Apotex Inc. and Apotex Corp. admit that the WHOIS results for apotexcorp.com available *via* the website www.networksolutions.com list Apotex, 150 Signet Drive Weston, ON M9L 1T9 CA as the registrant for the domain name www.apotexcorp.com and list Maury Gilman as the "Administrative Contact, Technical Contact." Apotex Inc. and Apotex Corp. further admit that the website www.apotex.com/us/en can be accessed via the website http://www.apotex.com/global/default.asp and/or the website http://www.apotexcorp. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

21. On information and belief, Apotex describes itself as a worldwide pharmaceutical company employing a global strategy of vertical integration. Apotex further describes itself as the largest pharmaceutical company in Canada, serving customers and partners in the U.S. market as well as in 115 countries globally. Apotex describes itself as a leader in the North American generic pharmaceutical market in terms of prescriptions filled, sales volume, and value, and its preference is to develop, manufacture, and market its own products—from API to finished dosage form to marketing and distribution.

ANSWER: Apotex Inc. and Apotex Corp. admit that the website www.apotex.com contains statements regarding Apotex Inc. and Apotex Corp. and the Court is referred to that website for a full and complete statement of its contents. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

22. On information and belief, the Florida Department of State Division of Corporations lists, as Apotex Corp.'s corporate address, Apotex Inc.'s address in Canada. In addition, Apotex Corp.'s 2010 For Profit Corporation Annual Report filed with the Florida Secretary of State, provides a mailing address of "c/o 150 Signet Drive, Weston, Ontario Canada M9L 1T9, ON M9L1T9" and lists only Bernard C. Sherman and Jack Kay as its officers and directors. On information and belief, Bernard C. Sherman is Chairman of the Board, Director, and Chief Executive Officer of Apotex Inc., and Jack Kay is President and Chief Operating Officer of Apotex Inc.

ANSWER: Apotex Inc. and Apotex Corp. admit that the website for the Florida Department of State Division of Corporations currently lists 2400 N Commerce Parkway, Suite 400, Weston, Florida 33326 as the Principal Address for Apotex Corp. and C/O 150 Signet Drive, Weston, Ontario Canada 1T9 ON M9L1T-9 as the mailing address. Apotex Inc. and Apotex Corp. further admit that Apotex Corp.'s 2010 Annual Report available on the website of the Florida Department of State Division of Corporations, provides an address of 2400 N Commerce Parkway, Suite 400, Weston, Florida 33326 as the principal place of business for Apotex Corp. and lists 150 Signet Drive, Weston, Ontario Canada M9L 1T9, ON M9L1T9 as a mailing address. Apotex Inc. and Apotex Corp. further admit that Bernard C. Sherman and Jack Kay are listed under the heading "Officers and Directors" on Apotex Corp.'s 2010 For Profit Corporation Annual Report available on the website of the Florida Department of State Division of Corporations. Apotex Inc. and Apotex Corp. further admit that Bernard C. Sherman is the Chairman and Chief Executive Officer of Apotex Inc., and Jack Kay is President and Chief

Operating Officer of Apotex Inc. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

23. On information and belief, Apotex Corp. is the U.S. agent for Apotex Inc. for purposes of making regulatory submissions to the FDA, including ANDA No. 20-1514 at issue in this litigation. In particular, Apotex Inc. has acted in concert with Apotex Corp. with respect to the preparation and filing of ANDA No. 20-1514 for Apotex's generic armodafinil products, and in preparation to sell those products in the United States and in this judicial district. *See infra* ¶ 30.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. served as the authorized U.S. agent for ANDA No. 20-1514 pursuant to 21 C.F.R § 314.50(a)(5). Except as specifically admitted herein, Apotex Inc. and Apotex Corp. the remaining allegations of this Paragraph.

24. On information and belief, Apotex Inc. and Apotex Corp. have a nearer than arm's length relationship such that Apotex Corp.'s contacts with Delaware can be imputed to Apotex Inc. For at least this reason, jurisdiction over Apotex Inc. is proper in this District.

ANSWER: Denied, except to state that Apotex Inc. and Apotex Corp. consent to jurisdiction in the United States District Court for the Southern District of Florida for the limited purposes of this litigation.

BACKGROUND

25. Cephalon, Inc. is the holder of approved New Drug Application ("NDA") No. 21-875 for the use of Nuvigil® (armodafinil) tablets in 50 mg, 150 mg, and 250 mg dosage strengths, as indicated to improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, and shift work sleep disorder.

ANSWER: Apotex Inc. and Apotex Corp. admit that the electronic version of the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as "the Orange Book"), identifies Cephalon as the applicant for NDA No. 21-875 for Nuvigil® (armodafinil) tablets in 50 mg, 150 mg, and 250 mg dosage strengths. Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

26. Cephalon France is the owner by assignment, and has the right to sue for infringement, of U.S. Patent No. 7,132,570 B2 ("the '570 patent"), entitled "Method for the Production of Crystalline Forms and Crystalline Forms of Optical Enantiomers of Modafinil." The '570 patent was duly and legally issued by the United States Patent and Trademark Office on November 7, 2006. A true and correct copy of the '570 patent is attached as Exhibit A.

ANSWER: Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is required, Apotex Inc. and Apotex Corp. admit that the title "Method for the Production of Crystalline Forms and Crystalline Forms of Optical Enantiomers of Modafinil" appears on the face of the '570 Patent; November 7, 2006 is the issue date listed on the face of the '570 Patent; Cephalon France is listed as the assignee on the face of the '570 Patent; and what purports to be a copy of the '570 Patent is attached to the Complaint as Exhibit A. Apotex Inc. and Apotex Corp. expressly deny that the '570 Patent was "duly and legally issued." Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

27. Cephalon, Inc. is the owner by assignment, and has the right to sue for infringement, of U.S. Reissued Patent No. RE37,516 E ("the '516 patent"), entitled "Acetamide Derivative Having Defined Particle Size." The '516 patent was duly and legally issued by the United States Patent and Trademark Office on January 15, 2002. A true and correct copy of the '516 patent is attached as Exhibit B.

ANSWER: Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, Apotex Inc. and Apotex Corp. admit that the title "Acetamide Derivative Having Defined Particle Size" appears on the face of the '516 Patent; January 15, 2002 is the issue date listed on the face of the '516 Patent; Cephalon, Inc. is listed as the assignee on the fact of the '516 Patent; and what purports to be a copy of the '516 Patent is attached to the Complaint as Exhibit B. Apotex Inc. and Apotex Corp. expressly deny that the '516 Patent was "duly and legally issued." Apotex Inc. and Apotex Corp. are without knowledge

and information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

28. Upon information and belief, Apotex filed ANDA No. 20-1514 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, and sale of armodafinil tablets in 50 mg, 150 mg, and 250 mg dosage strengths ("Apotex's generic armodafinil products") before the expiration of the '570 and '516 patents (collectively the "patents-in-suit"). On information and belief, as part of its ANDA, Apotex filed a "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the patents-in-suit are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's generic armodafinil products that are the subject of Apotex's ANDA No. 20-1514.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted an ANDA No. 20-1514 to the FDA seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Apotex Inc.'s proposed product, Armodafinil 50 mg, 150 mg, and 250 mg tablets (hereinafter "Apotex's proposed product") prior to expiration of U.S. Patent No. RE 37,516, U.S. Patent No. 7,132,570, and U.S. Patent No. 7,297,346. Apotex Inc. and Apotex Corp. further admit that ANDA No. 20-1514 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the above referenced patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the proposed product for which ANDA No. 20-1514 is submitted. ("Paragraph IV certification"). Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

29. Apotex caused to be sent to Cephalon a letter ("the Notice Letter"), dated July 6, 2010, notifying Cephalon that Apotex had filed ANDA No. 20-1514 seeking approval to market Apotex's generic armodafinil products prior to the expiration of the patents-in-suit, and was providing information to Cephalon pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Cephalon received the Notice Letter on or about July 7, 2010.

ANSWER: Apotex Inc. admits that by letter dated July 6, 2010, Apotex notified Plaintiffs that it had filed an ANDA seeking FDA approval to market Apotex's Proposed Product, prior to expiration of U.S. Patent No. RE37,516, U.S. Patent No. 7,132,570, and U.S. Patent No. 7,297,346 and that it was providing information to Plaintiffs pursuant to 21 U.S.C. §

355(j)(2)(B)(ii) and 21 C.F.R. § 314.95. Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

30. The Notice Letter defined "Apotex" as "Apotex Corp. and Apotex Inc." and stated that "Apotex" had submitted ANDA No. 20-1514 to engage in the commercial manufacture, use, importation, offer for sale, or sale of "Apotex's proposed product."

ANSWER: Apotex Inc. and Apotex Corp. admit that the July 6, 2010 Notice Letter referred to Apotex Corp. and Apotex Inc. collectively as "Apotex." Apotex Inc. and Apotex Corp. deny that the collective reference to "Apotex" in the Notice Letter is a statement regarding the legal relationship between Apotex Inc. and Apotex Corp. and/or the corporate structure of the respective entities. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

COUNT I FOR INFRINGEMENT OF THE '570 PATENT

31. Cephalon incorporates by reference Paragraphs 1-30, above.

ANSWER: Apotex Inc. and Apotex Corp incorporate by reference the Answers to Paragraphs 1-30 as if fully set forth herein.

32. Apotex has filed or caused to be filed ANDA No. 20-1514 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Apotex's generic armodafinil products before the expiration of the '570 patent. On information and belief, Apotex also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '570 patent are invalid, unenforceable, or not infringed.

ANSWER: Apotex Inc. and Apotex Corp admit that Apotex Inc. submitted an ANDA No. 20-1514 to the FDA seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Apotex Inc.'s proposed product, Armodafinil 50 mg, 150 mg, and 250 mg tablets (hereinafter "Apotex's proposed product") prior to expiration of U.S. Patent No. RE37,516, U.S. Patent No. 7,132,570, and U.S. Patent No. 7,297,346. Apotex Inc. and Apotex Corp. further admit that ANDA No. 20-1514 contains a certification pursuant to 21 U.S.C. §

355(j)(2)(A)(vii)(IV) that the above-referenced patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the proposed product for which ANDA No. 20-1514 is submitted. ("Paragraph IV certification"). Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

33. By submitting ANDA No. 20-1514 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Apotex's generic armodafinil products before the expiration of the '570 patent, Apotex has infringed the '570 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

34. Upon information and belief, Apotex Inc. has acted in concert with Apotex Corp., actively supporting, participating in, encouraging, and inducing Apotex Corp.'s filing of ANDA No. 20-1514 for Apotex's generic armodafinil products, and in the preparation to sell in the United States Apotex's generic armodafinil products.

ANSWER: Denied.

35. Upon information and belief, Apotex intends, soon after the FDA has approved the ANDA, to begin manufacturing, importing, marketing, selling, and offering to sell Apotex's generic armodafinil products with a product insert that will direct physicians and patients in the use of Apotex's generic armodafinil products.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted an ANDA No. 20-1514 to the FDA seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Apotex Inc.'s proposed product, Armodafinil 50 mg, 150 mg, and 250 mg tablets (hereinafter "Apotex's proposed product") prior to expiration of U.S. Patent No. RE37,516, U.S. Patent No. 7,132,570, and U.S. Patent No. 7,297,346. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

36. Upon information and belief, Apotex's generic armodafinil products, when offered for sale, sold, and/or imported, and when used as directed, would directly infringe at least one of the claims of the '570 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

37. Upon FDA approval of Apotex's ANDA No. 20-1514, Apotex will infringe the '570 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Apotex's generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

ANSWER: Denied.

38. Upon information and belief, Apotex Inc. will actively aid, abet, encourage, and induce Apotex Corp. and others in the production, importation, sale, offer for sale, and use of Apotex's generic armodafinil products.

ANSWER: Denied.

39. Upon information and belief, Apotex Inc. and Apotex Corp. will both actively participate in the production, importation, sale, offer for sale, and use of Apotex's generic armodafinil products.

ANSWER: Denied.

40. Upon information and belief, the offer to sell, sale, and/or importation of Apotex's generic armodafinil products would actively induce infringement under 35 U.S.C. § 271(b) of at least one claim of the '570 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

41. Upon information and belief, Apotex had knowledge of the '570 patent and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '570 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

42. As a result of Apotex's infringement of the '570 patent, Cephalon has been and will continue to be damaged unless said infringement is enjoined by this Court. Cephalon has no adequate remedy at law.

ANSWER: Denied.

COUNT II FOR INFRINGEMENT OF THE '516 PATENT

43. Cephalon incorporates by reference Paragraphs 1-42, above.

ANSWER: Apotex Inc. and Apotex Corp. incorporate by reference the Answers to Paragraph 1-42 as if fully set forth herein.

44. Apotex has filed or caused to be filed ANDA No. 20-1514 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Apotex's generic armodafinil products before the expiration of the '516 patent. On information and belief, Apotex also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '516 patent are invalid, unenforceable, or not infringed.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted ANDA No. 20-1514 to the FDA seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Apotex Inc.'s proposed product, Armodafinil 50 mg, 150 mg, and 250 mg tablets (hereinafter "Apotex's proposed product") prior to expiration of U.S. Patent No. RE37,516, U.S. Patent No. 7,132,570, and U.S. Patent No. 7,297,346. Apotex Inc. and Apotex Corp. further admit that ANDA No. 20-1514 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the above-referenced patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the proposed product for which ANDA No. 20-1514 is submitted. ("Paragraph IV certification"). Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this paragraph.

45. By submitting ANDA No. 20-1514 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Apotex's generic armodafinil products before the expiration of the '516 patent, Apotex has infringed the '516 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

46. Upon information and belief, Apotex Inc. has acted in concert with Apotex Corp., actively supporting, participating in, encouraging, and inducing Apotex Corp.'s filing of ANDA No. 20-1514 for Apotex's generic armodafinil products, and in the preparation to sell in the United States Apotex's generic armodafinil products.

ANSWER: Denied.

47. Upon information and belief, Apotex intends, soon after the FDA has approved the ANDA, to begin manufacturing, importing, marketing, selling, and offering to sell Apotex's generic armodafinil products with a product insert that will direct physicians and patients in the use of Apotex's generic armodafinil products.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted an ANDA No. 20-1514 to the FDA seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Apotex Inc.'s proposed product, Armodafinil 50 mg, 150 mg, and 250 mg tablets (hereinafter "Apotex's proposed product") prior to expiration of U.S. Patent No. RE37,516, U.S. Patent No. 7,132,570, and U.S. Patent No. 7,297,346. Except as specifically admitted herein, Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

48. Upon information and belief, Apotex's generic armodafinil products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '516 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

49. Upon FDA approval of Apotex's ANDA No. 20-1514, Apotex will infringe the '516 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Apotex's generic armodafinil products in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c).

ANSWER: Denied.

50. Upon information and belief, Apotex Inc. will actively aid, abet, encourage, and induce Apotex Corp. and others in the production, importation, sale, offer for sale, and use of Apotex's generic armodafinil products.

ANSWER: Denied.

51. Upon information and belief, Apotex Inc. and Apotex Corp. will both actively participate in the production, importation, sale, offer for sale, and use of Apotex's generic armodafinil products.

ANSWER: Denied.

52. Upon information and belief, the offer to sell, sale, and/or importation of Apotex's generic armodafinil products would actively induce infringement under 35 U.S.C. § 271(b) of at least one claim of the '516 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

53. Upon information and belief, Apotex had knowledge of the '516 patent and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '516 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

54. Upon information and belief, the offer to sell, sale, and/or importation of Apotex's generic armodafinil products would contributorily infringe under 35 U.S.C. § 271(c) at least one of the claims of the '516 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

55. As a result of Apotex's infringement of the '516 patent, Cephalon has been and will continue to be damaged unless said infringement is enjoined by this Court. Cephalon has no adequate remedy at law.

ANSWER: Denied.

*****

Apotex Inc. and Apotex Corp. deny all remaining allegations not specifically admitted herein. Apotex Inc. and Apotex Corp. further deny that Plaintiffs are entitled to the relief requested, or to any relief whatsoever.

DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Defendant Apotex Inc. and Apotex Corp. aver and assert the following defenses to the Complaint.

First Defense: Non-Infringement

1. Apotex Inc. and Apotex Corp. aver that they do not infringe, contribute to infringement, or induce infringement, nor have they done so in the past, of any valid and enforceable claim of the '570 Patent or the '516 Patent (collectively, the "Asserted Patents").

Second Defense: Invalidity

2. Apotex Inc. avers that the Asserted Patents are invalid on the grounds specified in United States Code, Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or 251.

Third Defense: Unenforceability of the '516 Patent

3. Apotex Inc. and Apotex Corp. aver that the '516 Patent is unenforceable due to the inequitable conduct of one or more persons who owed a duty of candor to the PTO with respect to the '516 Patent who, with the intent to deceive the PTO violated their duty of candor to the PTO by intentionally withholding material information and by making affirmative misrepresentations to the PTO during the prosecution of the '516 Patent

4. Details of the allegations of inequitable conduct are set forth in Count III of the Counterclaims below.

Fourth Defense: Patent Misuse

5. Apotex Inc. and Apotex Corp. aver that the '516 Patent is invalid and unenforceable because it was obtained fraudulently and by inequitable conduct.

6. Plaintiffs knew or should have known that the '516 Patent was invalid and/or unenforceable. Further evidentiary support for this allegation is likely to be identified after a reasonable opportunity for further investigation and discovery.

7. Plaintiffs submitted the '516 Patent to the FDA to be listed in the Orange Book as covering Nuvigil®. Plaintiffs also have commenced this infringement action against Apotex Inc. and Apotex Corp.

8. Knowing that the '516 Patent was unenforceable, Plaintiffs' efforts to enforce the '516 Patent by infringement suits and listing the '516 Patent in the Orange Book constitute patent misuse.

COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp. for their Counterclaims against Cephalon, Inc. and Cephalon France (collectively, "Cephalon"), alleges as follows:

NATURE OF THE ACTION

9. Apotex Inc. and Apotex Corp. bring claims for declaratory relief that United States Reissue Patent Nos. RE 37,516 ("the '516 Patent"), 7,132,570 ("the '570 patent"), and 7,297,346 ("the '346 Patent") (collectively "the Cephalon Patents") are invalid and not infringed by Apotex Inc. or Apotex Corp. so the Federal Food and Drug Administration ("FDA") can provide Apotex Inc. with final approval to market its generic version of the drug Nuvigil®, generically called armodafinil, under the Hatch-Waxman Act.

10. Apotex Inc. and Apotex Corp. further seek declaratory relief that the '516 Patent is unenforceable due to Plaintiffs' inequitable conduct.

11. Apotex Inc. and Apotex Corp. further seek declaratory relief that the '516 patent is unenforceable due to Cephalon's patent misuse.

Parties

12. Apotex Inc. is a Canadian corporation with a principal place of business at 380 Elgin Mills Road East, Richmond Hill Ontario Canada L4C 5H2.

13. Apotex Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

14. Cephalon Inc. purports to be a Delaware corporation having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

15. Cephalon France purports to be a société par actions simplifiée ("SAS") under the laws of France, a wholly-owned subsidiary of Cephalon, Inc., and located at 20 Rue Charles Martigny, 94701 Maisons-Alfort Cedex, France.

Jurisdiction and Venue

16. This Complaint arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

17. This Court has subject matter jurisdiction over this Complaint pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 and 35 U.S.C. § 271(e)(5).

18. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because Plaintiffs, *inter alia*, have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Apotex Inc. and Apotex Corp. in this District.

19. Venue is proper in this District pursuant 28 U.S.C. §§ 1391 and 1400(b).

Background

20. Cephalon, Inc. purports to be the holder of approved New Drug Application ("NDA") No. 21-875 for the use of Nuvigil® (armodafinil) tablets in 50 mg, 150 mg, and 250 mg dosage strengths.

21. Cephalon listed, *inter alia*, the '516, '570, and '346 Patents (collectively "the Cephalon Patents") in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as "the Orange Book") in connection with NDA 21-875. By listing these patents, Cephalon maintains that the patents claim Nuvigil®, or a method of using the drug, and that a suit for infringement could reasonably be brought against any generic manufacturer that attempts to seek approval to market a generic version of Nuvigil® before any of the afore mentioned patents expired.

22. Apotex Inc. submitted ANDA No. 20-1514 to the FDA seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Apotex Inc.'s proposed product, Armodafinil 50 mg, 150 mg, and 250 mg tablets (hereinafter "Apotex's Proposed Product") prior to expiration of the Cephalon Patents.

23. Because Apotex Inc. seeks FDA approval to market Apotex's Proposed Product before the expiration of the '516, '570, and '346 Patents, Apotex Inc.'s ANDA No. 20-1514 contains a certification that the Cephalon Patents are invalid and/or will not be infringed by the manufacture, use, or sale of the proposed product for which ANDA No. 20-1514 is submitted. pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification").

24. By letter dated July 6, 2010 Apotex provided Cephalon the statutorily-mandated notice letter of its Paragraph IV Certification on each of the '516, '570, and '346 Patents. This notice letter included a statement of the factual and legal bases for its opinion that the '516, '570,

and '346 Patents are invalid and/or will not be infringed by the manufacture, use, or sale of the proposed product for which ANDA No. 20-1514 is submitted.

25. On or about August 19, 2010, Cephalon filed a complaint against Apotex Inc. and Apotex Corp. in this district alleging infringement of the '570 and '516 Patents. Cephalon did not allege that Apotex Inc.'s ANDA No. 20-1514 would infringe the '346 Patent or that upon FDA approval of ANDA No. 20-1514, the importation, manufacture, use, offer to sell, or sale of Apotex's Proposed Product would infringe any of the claims of the '346 Patent. Cephalon Inc. is listed as the assignee on the face of the '346 patent.

26. 21 U.S.C. § 355(j)(5)(C) allows an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of an Orange Book listed patent if the NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification. Specifically, a generic manufacturer, such as Apotex Inc., that has submitted an ANDA containing a Paragraph IV certification on a patent is entitled to bring and maintain a declaratory judgment action against the NDA holder/patent owner on that patent if the following have occurred: (1) 45 days have passed since the paragraph IV certification was received by the NDA holder/patent owner; (2) neither the NDA holder nor the patent owner has filed a suit for patent infringement on the patent subject to the Paragraph IV certification within the 45-day period; and (3) an offer of confidential access to the ANDA is included in the notice of Paragraph IV certification provided to the NDA holder/patent owner. *See* 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc); *see also* 35 U.S.C. § 271(e)(5).

27. Since Cephalon was provided the offer to confidential access to Apotex Inc.'s ANDA pursuant to 21 U.S.C. § 355(i)(5)(C)(i)(III), and Cephalon did not assert the '346 patent within 45 days following receipt of Apotex's Paragraph IV Notice letter, Apotex Inc. is

statutorily permitted to file and maintain a declaratory judgment action to obtain patent certainty on the '346 Patent. *See* 21 U.S.C. § 355(j)(5)(C); *see also* 35 U.S.C. § 271(e)(5).

28. Accordingly, a real, actual, and justiciable controversy exists between Apotex Inc. and Cephalon regarding the invalidity and/or unenforceability of the Cephalon Patents and Apotex's non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Count I: Declaratory Judgment of Invalidity of the '346, '570, and '516 Patents

29. Apotex Inc. and Apotex Corp. adopt by reference, repeat, and reallege their specific responses and averments in Paragraphs 1-28 as though fully set forth herein.

30. The claims of the Cephalon Patents are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, 112, and/or 251.

Count II: Declaratory Judgment of Non-Infringement of the '346, '570, and '516 Patents

31. Apotex Inc. and Apotex Corp. adopt by reference, repeat, and reallege their specific responses and averments in Paragraphs 1-30 above as though set forth fully herein.

32. Apotex Inc. and Apotex Corp. do not infringe, contribute to the infringement of, or induce the infringement of any valid claim of the Cephalon Patents.

Count III: Declaratory Judgment of Unenforceability of the '516 Patent

33. Apotex Inc. and Apotex Corp. adopt by reference, repeat, and reallege their specific responses and averments in Paragraphs 1-32 above as though set forth fully herein.

34. Modafinil is an acetamide derivative. Both the compound modafinil and the neuropsychopharmacological profile of modafinil have been known since at least the late 1980s.

35. On or about October 6, 1994, Cephalon scientists Peter Grebow, Vincent Corvari, and David Strong filed United States Patent Application Serial No. 08/319,124 ("the '124 Application") titled "Acetamide Derivative Having Defined Particle Size" with the United States Patent and Trademark Office ("PTO"). The '124 Application could not validly claim the compound modafinil because the compound modafinil was disclosed in the prior art.

36. In conjunction with filing the '124 Application, the named inventors (i.e., Grebow, Corvari and Strong) assigned their interests to Cephalon and submitted declarations acknowledging their duty of candor (i.e., the duty to disclose all material information) to the PTO, and affirming that they were the true and properly named inventors for the '124 Application.

37. This duty of candor extended to all named inventors, as well as to others, such as patent attorneys and declarants, substantively involved in the prosecution of the '124 Application.

38. On April 8, 1997, the '124 Application issued as United States Patent No. 5,618,845 ("the '845 Patent").

39. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that on or before April 1, 1999, Cephalon concluded that the '845 Patent was wholly or partly inoperative or invalid; and that Cephalon sought to remedy perceived defects in the '845 Patent by filing a reissue application ("the '166 Application").

40. The filing of the '166 Application triggered new duties of candor for those individuals substantively involved in the prosecution of the '166 Application. On January 15, 2002, the PTO issued the '516 Patent and Cephalon surrendered the '845 Patent. The '516 Patent

term will expire on October 6, 2014. The FDA-granted pediatric exclusivity of the '516 Patent will expire on April 6, 2015.

41. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that despite representations, declarations, and/or suggestions to the contrary made during the prosecution of the '845 and'516 Patents (collectively the "Cephalon Particle Size Patents"), the modafinil compositions and methods claimed in the Cephalon Particle Size Patents were manufactured and developed by scientists at Labortoire L. Lafon ("Lafon"), rather than scientists at Cephalon; that the named inventors of the '845 Patent and the prosecuting attorneys did not inform the PTO about this material information during the prosecution of the '845 Patent; that this material information was intentionally withheld from the PTO; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

42. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that during the prosecution of the '845 Patent, the named inventors and/or the prosecuting attorneys of the Cephalon Particle Size Patents did not inform the PTO that Lafon sold and delivered modafinil tablets to Cephalon, prior to the Cephalon Particle Size Patents' critical date of October 6, 1993, under a Supply Agreement and a License Agreement executed in January 1993; that the modafinil tablets and modafinil active pharmaceutical ingredient ("API") sold and delivered to Cephalon prior to the critical date fall within some, if not all, of the composition claims recited in the Cephalon Particle Size Patents; that the sale and delivery of modafinil tablets and modafinil API under the Supply Agreement were highly material to patentability and were intentionally withheld by individuals who owed a duty of

candor to the PTO; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

43. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that during the prosecution of the '845 Patent, the named inventors and/or the prosecuting attorneys for the Cephalon Particle Size Patents intentionally misrepresented in the patent specification and in Peter Grebow's September 26, 1995 declaration that certain domestic and foreign clinical trials had followed the same protocol, when the foreign clinical trial conducted by Lafon actually administered half of the daily dose of modafinil in each of two daily doses, but the domestic clinical trial conducted by Cephalon administered the entire daily dose in a single dose; that during patent prosecution, Cephalon relied upon the existence of purported differences in adverse effects in the domestic and foreign trials in support of patentability, without telling the Examiner about the critical protocol change; that the protocol change was material in part because it offered an explanation for the alleged adverse effects different than the explanation advanced by Cephalon in support of patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

44. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that the named inventors and/or the prosecuting attorneys misrepresented to the PTO in the specifications for the Cephalon Particle Size Patents that the adverse events observed in the domestic clinical trial at 800 mg doses were completely unexpected; that Peter

Grebow, a named inventor, further intentionally misled the PTO when he reiterated that contention in his September 26, 1995 declaration in support of patentability; that it was actually Lafon who informed Cephalon in February 1993 that a single 600 mg dose of modafinil may cause adverse effects, a fact specifically known to Peter Grebow; that the named inventors reported in the specification that no clinically significant adverse events occurred in the foreign clinical trials conducted by Lafon; that numerous serious adverse events were observed during those foreign clinical trials; that Peter Grebow was aware of those instances of adverse events and even forwarded Lafon's "serious adverse event" information to a Canadian counterpart; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

45. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that during the '845 Patent prosecution, the named inventors and/or prosecuting attorneys at Cephalon intentionally concealed from the PTO that the domestic clinical trial described in the Cephalon Particle Size Patents, which used modafinil compositions covered by at least one of the composition claims, and which followed the method of administration falling within at least one of the method claims, occurred prior to both the critical date and the alleged conception date; that the subjects of the first United States clinical trial were members of the public, and they were under no obligation of confidentiality to Cephalon or the clinical investigators; that the non-confidential, public clinical trial was material to patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

46. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that during the prosecution of the '845 Patent, the named inventors and/or

prosecuting attorneys intentionally misrepresented to the PTO that the dog plasma level data discussed in the Cephalon Particle Size Patents demonstrated that the claimed small particle modafinil compositions resulted in higher peak plasma levels than the large particle modafinil compositions of the prior art; that notwithstanding their representations to the PTO, the named inventors and prosecuting attorneys knew that the comparative test results were not statistically significant; that Cephalon's DM-93-014 report to the FDA, completed at least as early as November 8, 1996 (i.e., while the '845 Patent was still pending and before the '516 Patent was filed), included representations directly contradictory to those made to the PTO; that the DM-93-014 report concluded that there was no statistically significant difference in the peak plasma levels as a function of modafinil particle size; that Cephalon agents with a duty of candor intentionally withheld the FDA report and the contradictory representations therein from the PTO; that during the prosecution of the '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

47. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that during the prosecution of the '845 Patent, the named inventors and/or prosecuting attorneys of the Cephalon Particle Size Patents intentionally withheld the fact that Lafon had already considered the importance of maintaining particle size controls over modafinil drug product prior to Cephalon's alleged invention; that Lafon provided Cephalon with particle size information for all of the lots of modafinil API that Lafon sold and delivered to Cephalon, including API Lot 003; that the specifications of the Cephalon Particle Size Patents misled the PTO examiners because they give the false impression that Cephalon was the first to measure particle size for modafinil and the first to recognize the importance of particle size; that the

named inventors and their attorneys also misrepresented to the PTO that one or more of the named inventors had discovered that the dissolution rate of modafinil increases with a decrease in particle size; that Lafon scientists discovered the relationship between modafinil dissolution rate and particle size in 1989; that Lafon had communicated the relevant dissolution and particle size data to Cephalon in March 1993; that Peter Grebow represented to the PTO that there were no publications suggesting that the utility of modafinil could be improved by reducing its particle size when he knew of a document published in September 1993, more than one year prior to the filing date, which suggests that modafinil bioavailability differences may be caused by the particle size distribution; that these misrepresentations and omissions were material to patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

48. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that the named inventors and/or prosecuting attorneys intentionally withheld the fact that Lafon scientists and others in Europe developed the protocols for and performed the foreign clinical studies discussed in the Cephalon Particle Size Patents as well as assisted the named inventors in the development of the protocol used in the U.S. clinical trial discussed in the Cephalon Particle Size Patents; that these facts were material to patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

49. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that the named inventors and/or prosecuting attorneys intentionally withheld

the fact that none of the named inventors had any role in the development of the early and late lot modafinil API and tablets discussed in the Cephalon Particle Size Patents, including, inter alia, the tablets (Lot 006) manufactured from Lafon lot L-1 (003) API; that the failure to disclose Lafon's role in the alleged invention misled the PTO examiners because it gave the false impression that the named inventors developed the modafinil tablets made from lot L-1 (003) API; that these facts were material to patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

50. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that the named inventors and/or prosecuting attorneys intentionally withheld the fact that the named inventors had no role in the foreign clinical study discussed in the specifications of the Cephalon Particle Size Patents; that this study was the work of Lafon scientists and others in Europe; that this failure to disclose the true origin of this study misled the PTO examiners because it gave the false impression that the foreign clinical study was the work of the named inventors; that these facts were material to patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

51. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that the named inventors and/or prosecuting attorneys intentionally withheld the fact that Lafon scientists gave the named inventors verbal and written information as well as substantial assistance in the development of the protocol that the named inventors used in the

U.S. clinical trial described in the Cephalon Particle Size Patents; that their failure to acknowledge Lafon's role in the development of the U.S. clinical trial protocol misled the PTO examiners because it gave the false impression that the named inventors alone developed the U.S. clinical trial protocol; that these facts were material to patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

52. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that the named inventors and/or prosecuting attorneys intentionally withheld the fact that modafinil Lot L-1 (003) API, which reads directly on the composition claims of Cephalon's Particle Size Patents, was manufactured and characterized by Lafon scientists, including its particle size distribution; that tablets made from Lot L-1 (003) API were developed and manufactured (i.e., invented) by Lafon scientists and subsequently sold and delivered to Cephalon prior to the October 6, 1993 critical date under the 1993 supply and license agreements; that these facts were material to patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the'516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO..

53. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that the named inventors and/or prosecuting attorneys intentionally withheld the fact that, during the prosecution of the '845 Patent, Lafon scientists provided information to Cephalon that explained the differences in bioavailability between the foreign and U.S. modafinil clinical trials may have been due to differences in particle size; that these facts were material to

patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

54. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that the named inventors and/or prosecuting attorneys intentionally withheld the fact that the named inventors were not the first to discover that modafinil is a very slightly water soluble compound; that they obtained this information from Lafon during the prosecution of the '845 Patent; that these facts were material to patentability; that Cephalon agents with a duty of candor had another opportunity to properly disclose these facts during the prosecution of the '516 Patent, but again intentionally declined to do so; and that Cephalon's agents committed the above acts with an intent to deceive the PTO.

55. A reasonable opportunity for further investigation or discovery is likely to lead to evidentiary support that the above-described omissions and misrepresentations were committed by Cephalon agents with an intent to deceive the PTO.

56. Based at least on the facts alleged in Paragraphs 33-55 above, the '516 Patent is unenforceable for inequitable conduct and the PTO would not have issued the '516 Patent but for the Cephalon agents' intentional misrepresentations and omissions to the PTO, which were made with an intent to deceive the PTO.

Count IV: Patent Misuse

57. Apotex Inc. and Apotex Corp. adopt by reference, repeat, and reallege their specific responses and averments in Paragraphs 1-56 above as though set forth fully herein.

58. The '516 Patent is invalid and was obtained improperly by inequitable conduct and/or fraud on the Patent and Trademark Office.

59. Knowing that the '516 Patent was unenforceable, Plaintiffs commenced this infringement action against Apotex Inc. and Apotex Corp. Plaintiffs' efforts to enforce the '516 Patent by suing for infringement and by seeking and maintaining the '516 patent listing in the Orange Book constitute patent misuse.

PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment and relief including:

A. A ruling in Apotex Inc. and Apotex Corp.'s favor on all Counts;

B. Declaring that Apotex Inc. and Apotex Corp. do not infringe, contribute to infringement, or induce infringement, nor have they done so in the past, of any valid and enforceable claim of United States Patent No. 7,132,570 B2, United States Reissued Patent No. RE37,516, or United States Patent No. 7,297,346.

C. Declaring that United States Patent No. 7,132,570 B2, United States Reissued Patent No. RE37,516, and United States Patent No. 7,297,346 are invalid.

D. Declaring that United States Reissued Patent No. RE37,516 is unenforceable due to inequitable conduct and/or fraud on the Patent and Trademark Office;

E. Declaring that United States Reissued Patent No. RE 37,516 is unenforceable due to patent misuse;

F. Awarding Apotex Inc. and Apotex Corp. costs and expenses in this action;

G. Declaring this case exceptional pursuant to 35 U.S.C. § 285 and granting Apotex Inc. and Apotex Corp. their attorney's fees; and

H. Awarding Apotex Inc. and Apotex Corp. any further and additional relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Apotex demands trial by jury for all issues triable by jury as a matter of right.

Dated: September 15, 2010.

Respectfully submitted,

s/Matthew S. Nelles

Matthew S. Nelles
Florida Bar No.: 009245
Email: mnelles@broadandcassel.com
Broad and Cassel
100 S.E. 3 Avenue, Suite 2700
Ft. Lauderdale, Florida 33394
Telephone: (954) 764-7060
Facsimile: (954) 761-8135
Attorney for Defendants/Counterclaim-Plaintiffs
APOTEX INC. and APOTEX CORP.

Robert B. Breisblatt
Florida Bar No. 145928
Email: robert.breisblatt@kattenlaw.com
Katten Muchin Rosenman LLP
525 W. Monroe Street
Chicago, Illinois 60661
Telephone: (312) 902-5480
Facsimile: (312) 577-8792
Attorney for Defendants/Counterclaim-Plaintiffs
APOTEX INC. and APOTEX CORP.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 15th day of September, 2010, a true and correct copy of the foregoing was electronically filed with the Clerk of Court using CM/ECF. The foregoing document is also being served this day on all counsel of record via transmission of Notices of Electronic Filing generated by CM/ECF.

BROAD AND CASSEL
100 S.E. 3 Avenue, Suite 2700
Ft. Lauderdale, Florida 33394
Telephone: (954) 764-7060
Facsimile: (954) 761-8135

By: /s/ Matthew S. Nelles
Matthew S. Nelles
Florida Bar No.: 009245